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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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08/951,733

10/16/1997

LEA ANNE HARRINGTON

A-433B

1921

21069

7590

09/26/2006

EXAMINER

MOORE, WILLIAM W

AMGEN INC.

MAIL STOP 28-2-C

ONE AMGEN CENTER DRIVE

THOUSAND OAKS, CA 91320-1799

ART UNIT

PAPER NUMBER

1656

DATE MAILED: 09/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

08/951,733

Applicant(s)

HARRINGTON ET AL.

Examiner

William W. Moore

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,5,7,8,11,13,14,17,26-30 and 33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,2,5,7,8,11 and 17 is/are allowed.
- 6) ☒ Claim(s) 13,14,26-29 and 33 is/are rejected.
- 7) ☒ Claim(s) 30 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                            |                                                                                         |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                           | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

## DETAILED ACTION

*Response to Amendment*

Applicant's Response filed 21 August 2006 has been entered, canceling claims 3, 4, 6, 9, 10, 12, 15, 16, 18-25, 31-32, 34, and 35 and amending claims 1, 2, 5, 7, 8, 11, 17, and 26-30. Claims 5 and 33 had previously been indicated as allowable. The claim cancellations and claim amendments, and Applicant's arguments in the Response that address the rejections of record of claims herein are persuasive in overcoming several of the rejections of record. In particular, the amendments of claims 1, 2, 5, and 26-28 remove the basis for the prior art rejections of record of claims herein under 35 U.S.C. § 102. This is because Cech et al., of record, do not disclose an isolated polynucleotide encoding either of the amino acid sequences of SEQ IDs NOs:14 or 20 where the amino acids at positions 36 and 39 in the melittin signal sequence-human telomerase fusion polypeptide of Cech et al. differ from the initiating methionine at position 1 and the serine at position 4 of SEQ IDs NOs:14 and 20 herein. The difference between the methionine at position 1 of SEQ IDs NOs:14 and 20 herein and the amino acid at the corresponding position in the prior art telomerase encoded by a polynucleotide of Cech et al. would have been obvious to one of ordinary skill in the art at the time the invention because substituting an eukaryotic signal peptide for the initiating methionine at position 1 in Applicant's SEQ IDs NOs:14 and 20, as Cech et al. had done, where such an artisan would have been considered this advantageous in producing a secreted, easily recovered, telomerase polypeptide not normally secreted by cells in Nature. There is no disclosure, and no suggestion, in the prior art of record, however, to prepare a nucleic acid sequence that specifies a serine at the position corresponding to position 4 in SEQ IDs NOs:14 and 20 herein rather than the threonine at the corresponding position in the telomerase polypeptide specified by a polynucleotide disclosed by Cech et al.

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Applicant's amendment in the Response of claim 17, the cancellation of claims 15, 16, and 18, and the arguments at pages 5 and 6 of the Response are persuasive in overcoming the rejection of record of claims herein under the first paragraph of 35 U.S.C. § 112, while the amendments of claims 29 and 30 in the Response filed 21 August 2006 avoid the rejection of record of these claims under the second paragraph of the statute. The amendments of claims 2, 7, 8, 11, and 17, and cancellation of claims 3, 9, 10, 12, 15, 16, and 18, avoid the rejection of record under 35 U.S.C. § 101 of claims herein for failing to describe statutory subject matter, i.e., an invention made by a person. A new ground of rejection is stated under 35 U.S.C. § 101, however, of certain claims herein that describe subject matter contrary to public policy.

#### *Claim Objections*

Claim 30 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 29. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). The subject matter described by claim 30 is indistinguishable from that described by claim 29 where a "mutant variant polypeptide of claim 30" is also a "variant polypeptide" of claim 29.

#### *Claim Rejections - 35 USC § 101*

35 U.S.C. § 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 13, 14, 26-28 and 33 are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter.

The subject matters of the cells described by claims 13, 14, and 33, and of methods practiced with such cells described by claims 26-28, is not limited to any particular set of

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transgenic animals, thus must construed according to the disclosures at page 12, lines 15-25, of the specification and is considered to reach transformed or transfected cells that may be the source of, or be comprised by, a transgenic animal which encompasses a human embryo or human egg. The claims therefore state non-statutory subject matter because a property right cannot be established in a person. As such, the recitation of the limitation "non-human" would be remedial. See 1077 O.G. 24, April 21, 1987. Such a term is present at page 12, lines 8, 16, and 26 of the specification.

*Allowable Subject Matter*

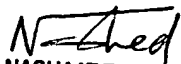
Claims 1, 2, 5, 7, 8, 11, 17, and 29 are allowed herewith, claim 30 is objected to for the reasons set forth above, and claims 13, 14, 26-28 and 33 would be allowable if amended to incorporate the exclusory term, "non-human", as disclosed at page 12 of the specification

*Conclusion*

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is 571.272.0933 and whose FAX number is 571.273.0933. The examiner can normally be reached Monday through Friday between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisory Primary Examiner, Dr. Kathleen Kerr, can be reached at 571.272.0931. The official FAX number for all communications for the organization where this application or proceeding is assigned is 571.273.8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571.272.1600.

William W. Moore  
20 September 2006

  
NASHAAT T. NASHED PHD.  
PRIMARY EXAMINER